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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,305	06/06/2002	Gene H MacDonald	5470.276	1963
20792	7590	10/31/2006	EXAMINER	
MYERS BIGEL SIBLEY & SAJOVEC			ANGELL, JON E	
PO BOX 37428			ART UNIT	
RALEIGH, NC 27627			PAPER NUMBER	
			1635	

DATE MAILED: 10/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/069,305

Applicant(s)

MACDONALD ET AL.

Examiner

Jon Eric Angell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 1-26 and 33-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
- Paper No(s)/Mail Date 2/02;11/02;11/04;9/05.

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

This Action is in response to the communication filed on 1/27/2005.

Claims 1-45 are currently pending in the application and are addressed herein.

Election/Restrictions

Applicant's election with traverse of Group V (claims 27-32) and the species primates in the reply filed on 10/27/2005 is acknowledged. The traversal is on the ground(s) that the invention is based on allegedly novel concept of administering an alphavirus vector in the presence of an antibody that binds thereto. Applicants acknowledge that administration of an antibody to a subject that already has antibodies (e.g., claim 36) is one way of achieving this (see page 2 of the response filed 1/27/2005). Applicant's arguments are not found persuasive because the concept of administering an alphavirus vector in the presence of an antibody that binds thereto (e.g., claim 36) is not novel as evidenced by the Parrington, et al. (previously cited). Furthermore, although Parrington et al. is sufficient to show that concept of the invention is not novel, it is also noted that administering an alphavirus vector and an antibody which specifically binds thereto is also not novel as indicated herein.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-26 and 33-45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 1/27/2005.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 2/22/2002, 11/12/2002, 11/03/2004 and 9/28/2005 are acknowledged. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,789,245 (Dubensky et al.) in view of Ohno et al. (Nat. Biotech. 1997).

Dubensky teaches an alphavirus vector which encodes and expresses a heterologous nucleic acid sequence as well as methods of using said vector for prophylactic and/or therapeutic

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purposes. For instance, Dubensky teaches administering the alphavirus vector which expresses a therapeutic protein to a human for prophylactic and/or therapeutic treatment of disease (e.g., see column 2, lines 57-67; column 3, lines 53-67; column 4, lines 1-41; column 7, lines 60-67; column 8, lines 1-6 and 41-67; etc.). Dubensky also teaches that the alphavirus vector can be modified such that it has a “modified envelope” which can be useful for targeting the vector to a specific tissue or cell type (e.g., see Example 9 columns 115-119). Specifically, Dubensky teaches:

“Furthermore, the foregoing technique can be used to create a recombinant alphavirus particles with envelope proteins that recognize Fc portions of antibodies. Monoclonal antibodies which recognize only preselected target cells are then bound to such Fc receptor-bearing alphavirus vector particles, such that the vector particles bind to and infect only those preselected target cells (for example, tumor cells).” (See column 119, lines 49-51).

Dubensky does not explicitly teach how to make such a modified alphavirus particle.

Ohno teaches a cell-specific targeted Sindbis virus vector which displays IgG-binding domains of protein A such that the modified Sindbis virus can transfect specific cancer cells when used in conjunction with antibodies that bind to the modified Sindbis vector and which also react with cancer cells (e.g., see abstract; Figure 1; Figure 3; Figure 4; Table 1; etc.). It is noted that the vector and antibody are administered to the cells concurrently in a single formulation.

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Dubensky and Ohno to create the claimed method for treating cancer in a human subject with a reasonable expectation of success.

The motivation to combine the references to create claimed invention is provided by Dubensky who specifically teaches that the alphavirus vector can be modified to express an

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antibody binding protein and further using an antibody which binds to the modified alphavirus vector and also binds to a target cell (e.g., see column 119, lines 49-51). Ohno also provides evidence of a reasonable expectation of success that the modified Sindbis virus (an alphavirus vector) would be able to transfect and express a heterologous sequence in a target cancer cell (e.g., see Figures 3 and 4).

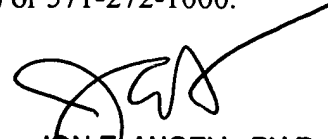
Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Mon-Fri, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



JON E. ANGELL, PH.D.
PRIMARY EXAMINER